

*Quality* means that the dietary supplement consistently meets the established specifications for identity, purity, strength, and composition, and limits on contaminants, and has been manufactured, packaged, labeled, and held under conditions to prevent adulteration under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the act.

*Quality control* means a planned and systematic operation or procedure for ensuring the quality of a dietary supplement.

*Quality control personnel* means any person, persons, or group, within or outside of your organization, who you designate to be responsible for your quality control operations.

*Representative sample* means a sample that consists of an adequate number of units that are drawn based on rational criteria, such as random sampling, and that are intended to ensure that the sample accurately portrays the material being sampled.

*Reprocessing* means using, in the manufacture of a dietary supplement, clean, uncontaminated components or dietary supplements that have been previously removed from manufacturing and that have been made suitable for use in the manufacture of a dietary supplement.

*Reserve sample* means a representative sample of product that is held for a designated period of time.

*Sanitize* means to adequately treat cleaned equipment, containers, utensils, or any other cleaned contact surface by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other microorganisms, but without adversely affecting the product or its safety for the consumer.

*Theoretical yield* means the quantity that would be produced at any appropriate step of manufacture or packaging of a particular dietary supplement, based upon the quantity of components or packaging to be used, in the absence of any loss or error in actual production.

*Water activity* ( $a_w$ ) is a measure of the free moisture in a component or dietary supplement and is the quotient of the water vapor pressure of the sub-

stance divided by the vapor pressure of pure water at the same temperature.

*We* means the U.S. Food and Drug Administration (FDA).

*You* means a person who manufactures, packages, labels, or holds dietary supplements.

#### **§ 111.5 Do other statutory provisions and regulations apply?**

In addition to this part, you must comply with other applicable statutory provisions and regulations under the act related to dietary supplements.

### **Subpart B—Personnel**

#### **§ 111.8 What are the requirements under this subpart B for written procedures?**

You must establish and follow written procedures for fulfilling the requirements of this subpart.

#### **§ 111.10 What requirements apply for preventing microbial contamination from sick or infected personnel and for hygienic practices?**

(a) *Preventing microbial contamination.* You must take measures to exclude from any operations any person who might be a source of microbial contamination, due to a health condition, where such contamination may occur, of any material, including components, dietary supplements, and contact surfaces used in the manufacture, packaging, labeling, or holding of a dietary supplement. Such measures include the following:

(1) Excluding from working in any operations that may result in contamination any person who, by medical examination, the person's acknowledgment, or supervisory observation, is shown to have, or appears to have, an illness, infection, open lesion, or any other abnormal source of microbial contamination, that could result in microbial contamination of components, dietary supplements, or contact surfaces, until the health condition no longer exists; and

(2) Instructing your employees to notify their supervisor(s) if they have or if there is a reasonable possibility that they have a health condition described in paragraph (a)(1) of this section that

could result in microbial contamination of any components, dietary supplements, or any contact surface.

(b) *Hygienic practices.* If you work in an operation during which adulteration of the component, dietary supplement, or contact surface could occur, you must use hygienic practices to the extent necessary to protect against such contamination of components, dietary supplements, or contact surfaces. These hygienic practices include the following:

(1) Wearing outer garments in a manner that protects against the contamination of components, dietary supplements, or any contact surface;

(2) Maintaining adequate personal cleanliness;

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with microorganisms) in an adequate hand-washing facility:

(i) Before starting work; and

(ii) At any time when the hands may have become soiled or contaminated;

(4) Removing all unsecured jewelry and other objects that might fall into components, dietary supplements, equipment, or packaging, and removing hand jewelry that cannot be adequately sanitized during periods in which components or dietary supplements are manipulated by hand. If hand jewelry cannot be removed, it must be covered by material that is maintained in an intact, clean, and sanitary condition and that effectively protects against contamination of components, dietary supplements, or contact surfaces;

(5) Maintaining gloves used in handling components or dietary supplements in an intact, clean, and sanitary condition. The gloves must be of an impermeable material;

(6) Wearing, where appropriate, in an effective manner, hair nets, caps, beard covers, or other effective hair restraints;

(7) Not storing clothing or other personal belongings in areas where components, dietary supplements, or any contact surfaces are exposed or where contact surfaces are washed;

(8) Not eating food, chewing gum, drinking beverages, or using tobacco products in areas where components,

dietary supplements, or any contact surfaces are exposed, or where contact surfaces are washed; and

(9) Taking any other precautions necessary to protect against the contamination of components, dietary supplements, or contact surfaces with microorganisms, filth, or any other extraneous materials, including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

**§ 111.12 What personnel qualification requirements apply?**

(a) You must have qualified employees who manufacture, package, label, or hold dietary supplements.

(b) You must identify who is responsible for your quality control operations. Each person who is identified to perform quality control operations must be qualified to do so and have distinct and separate responsibilities related to performing such operations from those responsibilities that the person otherwise has when not performing such operations.

(c) Each person engaged in manufacturing, packaging, labeling, or holding, or in performing any quality control operations, must have the education, training, or experience to perform the person's assigned functions.

**§ 111.13 What supervisor requirements apply?**

(a) You must assign qualified personnel to supervise the manufacturing, packaging, labeling, or holding of dietary supplements.

(b) Each supervisor whom you use must be qualified by education, training, or experience to supervise.

**§ 111.14 Under this subpart B, what records must you make and keep?**

(a) You must make and keep records required under this subpart B in accordance with subpart P of this part.

(b) You must make and keep the following records:

(1) Written procedures for fulfilling the requirements of this subpart B; and

(2) Documentation of training, including the date of the training, the type of training, and the person(s) trained.